

REMARKS/ARGUMENTS

The claims pending in the Application following entry of the foregoing amendments will be Claims 5 - 19.

Claims 1-4 have been cancelled above.

The rejections of Claims 1 and 2 under 35 U.S.C. §101 and 35 U.S.C. §112 (first paragraph) are moot in view of the cancellation of these claims above.

Newly submitted Claims 5 -19 are directed to methods of inhibiting the deposition of proteins on medical devices that are subject to prolonged exposure to proteins during use in or on the bodies of humans or other mammals. The methods include the step of distributing a NIPAM polymer on the surfaces of such medical devices (e.g., contact lenses or intraocular lenses). As discussed in greater detail below, this is a new use of NIPAM polymers that is neither disclosed nor suggested by the prior art.

The methods of Claims 5 - 19 are supported by the specification of the present application. In particular, the specification clearly describes and asserts the utility of NIPAM polymers for inhibiting the deposition of proteins on the surfaces of medical devices (see, e.g., lines 10-24 on page 6). Applicant therefore respectfully submits that the grounds asserted by the Examiner in connection with the above-cited rejections of Claims 1 and 2 are clearly not applicable to Claim 5 - 19.

Claims 1-4 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by or, in the alternative, under 35 U.S.C. §103 as allegedly being obvious over the following references:

- (1) Hoffman, et al. U.S. Patent No. 5,998,588;
- (2) Sudor, International Publication No. WO 02/30571;
- (3) Kidoaki, et al., "Thermoresponsive Structural Change of a Poly(N-isopropylacrylamide) Graft Layer Measured with an Atomic Force Microscope", Langmuir, 2001, pages 2402-2407;
- (4) Bohanon, et al., "Neural Cell Pattern Formation on Glass and Oxidized Silicon Surfaces With Poly (N-isopropylacrylamide), Vol. 8, No. 1, 1996, pages 19-39; or

- (5) Dong, et al., "Chapter 16 - Thermally Reversible Hydrogels", American Chemical Society Symposium, 1987, pages 236-244.

The above-identified references do not disclose the use of NIPAM polymers to inhibit the deposition of proteins on medical devices that are subject to prolonged exposure to proteins during use in or on the bodies of humans or other mammals. In particular, the references do not disclose the subject matter recited in Claims 5-19.

The present invention is particularly directed to the modification of surfaces that have an overall negative charge and are attracted towards positively charged proteins, such as lysozyme. The above-listed references do not address how one might modify such surfaces of medical devices, such as contact lenses.

The Hoffman, et al. reference discloses the coupling of NIPAM polymers to other molecules to form site specific conjugates. The invention described in this reference is directed to devices utilized in analytical chemistry procedures, rather than medical devices.

The Sudor reference is directed to substrates that are silicon (such as semiconductors), quartz, glass, ceramics or plastic. It does not mention medical devices.

The Langmuir reference also discloses the use of NIPAM polymers in the context of laboratory instruments. The polymers are graft polymerized on glass substrates on the tip of an AFM instrument. This reference focuses on the interaction of the tips with albumin and fibronectin. Although this article suggests that there are interactions that take place between pNIPAM and proteins, the surfaces involved are quite different from those of contact lenses or other medical devices.

Similarly, in the Bohanon, et al. reference, the surfaces specifically mentioned are glass or other silicon oxide surfaces. A coupling agent is utilized to modify and retain the pNIPAM on the surface. The use of pNIPAM to physically adsorb on the enclosed surfaces is not suggested.

The Dong, et al. reference is directed to the use of NIPAM polymers to form "catalytic hydrogels" that are utilized to control reactions. It does not disclose the use of NIPAM polymers to modify the surfaces of medical devices.

In view of the absence of any relevant teaching in the cited references regarding the modification of surfaces of medical devices, so as to inhibit the deposition of proteins on those surfaces, Applicants respectfully submit that these references clearly do not render the subject matter of Claims 5-19 obvious to a person skilled in the art of medical device surface modifications.

In view of the foregoing amendments and remarks, favorable reconsideration in the form of a Notice of Allowance is respectfully requested.

Respectfully submitted,
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